The American Antitrust Institute

January 18, 2011

Mr. Frederick K. Ohlrich
Clerk of the Court
Supreme Court of California
350 McAllister St.
San Francisco, CA 94102-3600

Re: *In re Cipro Cases I & II* (2011), No. S198616

Dear Mr. Ohlrich,

The American Antitrust Institute (AAI) submits this letter pursuant to Rule 8.500(g), respectfully requesting this Honorable Court to review the decision of Division 1 of the Fourth Appellate District in *In re Cipro Cases I & II* (2011), No. S198616 (200 Cal.App.4th 442). That decision would deprive the California courts of any meaningful ability to assess the anticompetitive effects in so-called "reverse payment" or "pay for delay" cases when brand name drug manufacturers and generic drug manufacturers agree not to compete with one another. The standard adopted by the Fourth Appellate District would take a severe toll on Californians, not only costing the California government and consumers hundreds of millions of dollars but also ultimately harming the public health and sacrificing human lives.[1] The appropriate standard for assessing reverse payment cases is an issue worthy of the attention of this Court.

I. Statement of Interest of Amicus Curiae

AAI is an independent non-profit educational, research, and advocacy organization devoted to advancing the role of competition in the economy, protecting consumers, and sustaining the vitality of the antitrust laws. AAI is managed by its Board of Directors, with the guidance of an Advisory Board that consists of more than 115 prominent antitrust lawyers, law professors, economists, and business leaders.[2] *See* http://www.antitrustinstitute.org. AAI frequently appears as amicus curiae in cases raising important antitrust issues, including, for example, in *Pacific Bell Telephone Co. v. linkLine Communications, Inc.*, 555 U.S. 438 (2009), in which it participated in oral argument before the United States Supreme Court. AAI has been deeply concerned about the problem of "pay for delay" settlements and the rulings of some courts (such as the court below) that effectively legalize such agreements. *See, e.g.,* Brief of

[1] *See* Thomas Rice & Karen Y. Matsuoka, *The Impact of Cost-Sharing on Appropriate Utilization and Health Status: A Review of the Literature on Seniors*, 61 MED. CARE RES. & REV. 415, 420, 427 (2004).

[2] The individual views of members of the Advisory Board may differ from the positions taken by AAI. One of the attorneys for the plaintiffs is a member of the Advisory Board, but played no role in the directors' deliberations over this brief or in its drafting or funding.

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Amici Curiae American Antitrust Institute and 26 Professors in Support of Appellants and Reversal, *In re K-Dur Antitrust Litigation*, No. 10-2287 (3d Cir. 2011), *available at* http://www.antitrustinstitute.org/content/activities-amicus-program.

II. This Court Should Grant Review

This action at its core involves an agreement not to compete. In this case, Bayer AG and Bayer Corporation ("Bayer") agreed to pay generic drug manufacturers almost $400 million to delay competition in the market for ciprofloxacin hydrochloride ("Cipro"), a popular antibiotic. Agreements among competitors not to compete are highly suspect under antitrust law. Justifiably so. They can provide a means for sellers to decrease the supply of a good or service and thereby to raise prices above competitive levels. Experts on antitrust doctrine from all perspectives—left, right and center—recognize agreements among competitors not to compete as posing a great danger.

The danger is particularly grave in the pharmaceutical industry, where ever-increasing prices not only impose a huge drag on the economy and deplete the public coffers, but scarcity can result in loss of life and limb. A study of twenty drugs, for example, found that each year of delayed generic entry costs "consumers and the government roughly $12 billion."[3] Another study found that an increase by $1 in the out-of-pocket cost of a drug resulted in people 65 or older buying 114 fewer tablets per year.[4] For those who cannot afford to purchase Cipro, a failure of treatment can result in a much more costly visit to an emergency room—often, again, imposing high costs on the public—as well as severe adverse medical consequences.

Agreements of the sort at issue in this case are sometimes called "reverse payments" and at other times "pay for delay." Each term captures part of the concern at issue. The payments are called "reverse" because the brand name drug manufacturer has accused the generic drug manufacturer of patent infringement, yet the brand manufacturer pays a sum of money in exchange for an agreement not to compete. Why would a patent holder pay a large sum to a party that allegedly is violating its legal rights? It does so out of fear that it will *lose* if it pursues legal action to a final judgment. By paying the generic drug manufacturer, the brand manufacturer increases the time during which it expects to enjoy supracompetitive profits. The reverse payment is a means of sharing some of those supracompetitive profits with the generic drug manufacturer.

The term "pay for delay" reflects precisely what it is that the brand manufacturer is purchasing. It buys a protracted period in which it can sells its drugs without competition, a period longer than it would expect to achieve if a court were to rule on the underlying merits of its patent claim. In other words, the payment reflects the purchase of a right to exclude one or more competitors *beyond* the period the brand drug manufacturer's legal rights would be expected to allow. In this case, Bayer's payment of almost $400 million means that it perceived

[3] C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 COLUM. L. REV. 629, 650 (2009).
[4] Jan Blustein, *Drug Coverage and Drug Purchases by Medicare Beneficiaries with Hypertension*, 19 HEALTH AFF. 219, 228 (2000).

itself as buying a very significant period of delayed competition. Otherwise, it would never have expended such a large sum of money.

Yet the lower courts in this action ruled that Bayer's actions were protected from any meaningful scrutiny under California's antitrust laws. The appellate court held plaintiffs would have to meet a very high standard to prevail—having to demonstrate either that Bayer obtained its patent by fraud or that the suit enforcing its patent rights was baseless. In effect, the court treated the "reverse payment" as virtually *per se*—or automatically—legal. That is an unusual departure from the ordinary antitrust standards that apply to potentially anticompetitive conduct, which range from the rule of reason (under which a court weighs the procompetitive and anticompetitive effects of conduct) to the *per se* rule (which condemns conduct as automatically illegal). Neither practical considerations nor formal doctrine requires such an anomalous approach.

As to practical considerations, one of the arguments in favor of reverse payments is that they facilitate settlement. But they seem rarely, if ever, necessary to achieve settlement. The vast majority of cases settle.[5] Even without reverse payments, a mechanism would be readily available by which a brand name drug manufacturer and a generic drug manufacturer could resolve a dispute over patent rights. They could simply agree to a delay in generic entry that reflects the relative strength of the patent claim. If, for example, the brand manufacturer claims a patent gives rise to six years of exclusivity and the generic that it provides no legitimate exclusivity at all, they could settle the dispute by, say, agreeing that generic entry will occur after three years.[6] Indeed, the evidence suggests settlements occur in patent dispute cases even when reverse payments are not possible. When for a brief period the prevailing law appeared to be that reverse payments were illegal, drug companies stopped agreeing to them but they continued to settle patent disputes at approximately the same rate as when reverse payments appeared to be legal.[7] All that a reverse payment is likely to do, then, is to change the terms of settlement, delaying the compromise date of generic entry to the benefit of the brand and generic drug manufacturers and to the detriment of consumers, the government, and the public health.

Another practical consideration is the difficulty in assessing which reverse payments are permissible. Various options are available to this Court in that regard. It could adopt a rule that reverse payments are *per se* illegal, as the Sixth Circuit has done.[8] If it did, drug manufacturers who are subject to California law would in all likelihood simply stop agreeing to reverse payments and settle by other means. Alternatively, the Court could use a presumption of illegality to simplify the analysis, as the Federal Trade Commission and many commentators

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[5] *See* Joshua P. Davis, *Applying Litigation Economics to Patent Settlements: Why Reverse Payments Should be Per Se Illegal*, 41 RUTG. L. J. 255, 262 & n. 28 (2009).
[6] *Id*. at 290-91.
[7] *Id*. at 295-97.
[8] *In re Cardizem CD Antitrust Litig*. (6th Cir. 2003) 332 F.3d 896; s*ee also* Davis, 41 RUTG. L. J. at 255; Maureen A. O'Rourke & Joseph F. Brodley, *An Incentives Approach to Patent Settlements*, 87 MINN. L. REV. 1767, 1781-82 (2003).

have suggested.[9] Or this Court could engage in a full rule of reason analysis, as the Eleventh Circuit has done and other commentators recommend.[10] Whichever of these standards is most attractive, AAI respectfully submits that this Court should not countenance behavior that so often is pernicious simply because of the difficulty of separating out when conduct is anticompetitive from when it is not. It would be better to rule the behavior is *per se* illegal if administrative ease is a primary goal.

Nor do we believe that federal preemption deprives this Court of the leeway to decide the best antitrust standard to apply to reverse payments. First, a patent grant gives rise only to a presumption of validity, not an authoritative ruling, and even that presumption is suspect given the high rate at which patents are invalidated.[11] Second, courts in the past have permitted inquiry into patent rights as relevant to a state law cause of action, *Dow Chem. Co. v. Exxon Corp*. (Fed. Cir.1998) 139 F.3d 1470, 1475, just as those rights could be relevant to assessing the procompetitive and anticompetitive effects of reverse payments. Third, reverse payments, by their nature, tend to occur when there has been no authority ruling on the validity of the federal patent rights at issue. It is the absence of such a ruling that creates the incentive for a reverse payment. And a ban—or limitation—on reverse payments would not prevent any party from enforcing its federal patent rights either through litigation or through settlement; it would merely prohibit or restrict reliance on a particular method of achieving settlement. Finally, this Court could adopt a rule that does not depend on an inquiry into the validity of the underlying patent, ruling, for example, that reverse payments are *per se* illegal.

Similarly, federal law does not require or support the notion that any settlement protecting the asserted scope of a patent should automatically be treated as permissible. To the contrary, the federal statutory regime governing drug patents, the Hatch-Waxman Act,[12] embodies a policy commitment *encouraging* generic drug manufacturers to test the patent rights of brand name drug manufacturers.[13] It would be inconsistent with that policy to allow brand and generic drug manufacturers to agree not to compete and to share monopoly profits any time there is a weak but not baseless claim for patent infringement. Indeed, California antitrust law would serve the policy behind the Hatch-Waxman Act if it were to scrutinize reverse payments.

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[9] *In re Schering Plough Corp*. (F.T.C. Dec. 18, 2003) No. 9297, *rev'd*, (11th Cir. 2005), 402 F.3d 1056; *see also* Michael Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 MICH. L. REV. 37, 41 (2009); C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 COLUM. L. REV. 629, 638 (2009).

[10] *Valley Drug Co., v. Geneva Pharmaceuticals, Inc.* (11th Cir. 2003) 344 F.3d 1294; s*ee also* Daniel A. Crane, *Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications*, 54 FLA. L. REV. 747, 779-96 (2002).

[11] *See* Douglas Lichtman & Mark A. Lemley, *Rethinking Patent Law's Presumption of Validity*, 60 STAN. L. REV. 45 (2007).

[12] The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984), commonly known as the Hatch-Waxman Act.

[13] *See* Carrier, 108 MICH. L. REV. at 41; Hemphill, 109 COLUM. L. REV. at 638; C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1614 (2006).

That scrutiny would not threaten federal patent rights. It would neither discourage brand name drug manufacturers from pursuing their patent rights in court nor prevent brand name and generic drug manufacturers from settling their disputes by compromising over the date of generic entry.

III. Conclusion

"Pay for delay" is an anticompetitive practice that has generated a rare consensus among experts in antitrust law. Academics from an extraordinarily broad range of theoretical and political perspectives all agree that reverse payments should *not* be deemed *per se* legal, although they disagree about whether they should be condemned as *per se* illegal, assessed under the rule of reason, or subjected to analysis involving presumptions.[14] No economic principle or state or federal law doctrine prevents this Court from condemning a practice that reason and analysis has shown to be anticompetitive in many instances. The legality of pay for delay is an issue of tremendous importance to the economy and public health. AAI respectfully submits that this Court should grant review in this case to decide when, if ever, reverse payments are legal under California antitrust law.

Sincerely,

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[14] Analyses of reverse payments—*none* of which endorsed the *per se* legal standard adopted by the courts below—include the sources cited in footnotes 3, 5, 8-10, & 13 *supra* as well as 1 HERBERT HOVENKAMP ET AL., IP AND ANTITRUST § 15.3a1(C) (2d ed. 2010); ROBIN COOPER FELDMAN, THE ROLE OF SCIENCE IN LAW 167 (2009); David W. Opderbeck, *Rational Antitrust Policy and Reverse Payment Settlements in Hatch-Waxman Patent Litigation*, 98 GEO. L. J. 1303 (2010); Joseph Farrell & Carl Shapiro, *How Strong Are Weak Patents?*, 98 AM. ECON. REV. 1347 (2008); Herbert Hovenkamp, *et al*., *Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN. L. REV. 1719 (2003).

[15] Institutional affiliation is for identification purposes only.